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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

Polymer DRS 317

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment and Energy.

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**Director
NICNAS**

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1631	Wurth Australia Pty Ltd	Polymer DRS 317	Yes	< 20 tonnes per annum	Component of chemical adhesives

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute toxicity, oral (Category 4)	H302 – Harmful if swallowed
Skin irritation (Category 2)	H315 – Causes skin irritation
Eye irritation (Category 2)	H319 – Causes serious eye irritation

Human health risk assessment

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment

Based on the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified polymer should be classified as follows:
 - Acute toxicity, oral (Category 4): H302 – Harmful if swallowed
 - Skin irritation (Category 2): H315 – Causes skin irritation
 - Eye irritation (Category 2): H319 – Causes serious eye irritation

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer as introduced in formulated products:
 - Automated processes where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced:
 - Avoid contact with skin and eyes
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
 - Gloves
 - Goggles
 - Protective clothing

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Storage

- The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer is intended for public use;
 - further toxicological and ecotoxicological information on the notified polymer has become available;

or

- (2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of chemical adhesives used in the construction industry, or is likely to change significantly;
 - the amount of polymer being introduced has increased, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Safety Data Sheet

The SDS of the products containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Wurth Australia Pty Ltd (ABN: 48 002 487 096)
Unit 2, 1 Healey Road
DANDENONG SOUTH VIC 3175

NOTIFICATION CATEGORY

Standard: Synthetic polymer with Mn < 1,000 g/mol (more than 1 tonne per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical endpoints, human health endpoints and environmental endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Palatal D100 V-01 (product containing the notified polymer at 45% concentration)
UM-H Comp A (product containing the notified polymer at 15 – 18% concentration)

MOLECULAR WEIGHT

Number Average Molecular Weight (Mn) is < 1,000 g/mol.

ANALYTICAL DATA

Reference NMR, IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 97%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Brown liquid*

Property	Value	Data Source/Justification
Melting Point	Not determined	Estimated to be high using EPI Suite
Boiling Point	Not determined	Estimated to be high using EPI Suite. The product containing the notified polymer at 45% concentration has an initial boiling point of 260 °C (SDS).
Density	Not determined	The product containing the notified polymer at 45% concentration is estimated to have a density of 1,090 kg/m ³ at 20 °C (SDS).
Vapour Pressure	Not determined	Estimated to be low using EPI Suite. The product containing the notified polymer at 45% concentration has a vapour pressure of < 0.01 kPa (SDS).

Property	Value	Data Source/Justification
Water Solubility	Not determined	Expected to have limited solubility in water based on its predominantly hydrophobic structure.
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionality. However, based on its assumed limited water solubility, it is expected to hydrolyse very slowly in the environmental pH range (4–9).
Partition Coefficient (n-octanol/water)	Not determined	Assumed to have a log Kow > 5 based on relatively high molecular weight
Adsorption/Desorption	Not determined	Expected to adsorb to soil, sediment and sludge, and has low mobility in soil based on its hydrophobicity
Dissociation Constant	Not determined	Contains no ready dissociable functional groups
Flash Point	Not determined	The product containing the notified polymer at 45% concentration has a flash point of > 110 °C (SDS).
Flammability	Not determined	-
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties

* Properties of Palatal D100 V-01 that contains the notified polymer at 45% concentration

DISCUSSION OF PROPERTIES

No detailed tests on physical and chemical properties of the notified polymer were submitted. The notified polymer will never be isolated from mixtures when synthesised and will only be imported as a component in end use adhesive products at 15 – 18% concentration.

Reactivity

The notified polymer contains pendent methacrylate functional groups and, when mixed with other components of the adhesive, is expected to undergo further polymerisation reactions to form a solid matrix. The reactions are intended by design as part of use patterns.

Physical hazard classification

Based on the limited physical-chemical data depicted in the above table, the notified polymer cannot be recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified polymer will not be manufactured or reformulated within Australia. It will be imported as a component in end use adhesive products which contain the notified polymer at concentrations of 15 – 18%.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	1	2	3	4	5
Tonnes	< 15	< 15	< 15	< 20	< 20

PORT OF ENTRY

Melbourne and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS

Wurth Australia Pty Ltd

TRANSPORTATION AND PACKAGING

The end-use adhesive products containing the notified polymer will be imported into Australia by sea and transported by road in cartridges of 300 mL and 410 mL sizes. The products containing the notified polymer will be distributed to industrial users in the construction sector.

USE

The notified polymer will be used as a component of a chemical adhesive used in the construction sector.

OPERATION DESCRIPTION

The finished adhesive products containing the notified polymer at concentration of $\leq 18\%$ will be used in the construction sector for physically anchoring threaded rods, reinforcing bars or rod sleeves into concrete and masonry. The adhesive is resin mortar based and expected to be chemically stable under normal construction conditions. The adhesive products containing the notified polymer will be applied by hand tools, battery operated tools or pneumatic tools with static mixers. Once the components of the adhesive are mixed, the curing is expected to complete within several minutes to form a solidified matrix.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Dock workers	4	10
Transport workers	3	10
On-site storage workers	4	300
Construction workers	8	100

EXPOSURE DETAILS

Transport and storage

Exposure of transport and storage workers to the notified polymer is not expected, except in the event of accidental spill or breach of container. Workers are expected to wear appropriate PPE, such as gloves, protective clothing, and respiratory protection if there is inadequate ventilation, in order to minimise the potential for exposure.

End use

During construction, workers may be dermally exposed to the adhesive containing the notified polymer at $\leq 18\%$ concentration. Accidental ocular exposure is also possible. Exposure to the notified polymer is expected to be limited, due to the use of special tools, automated equipment and appropriate PPE. Construction workers may also come into contact with cured adhesive containing the notified polymer. However at this stage, the notified polymer will be bound within a matrix of cured solid material and is not expected to be available for further exposure.

6.1.2. Public Exposure

The notified polymer will be for industrial use only, and will not be available to the public. Public may come into contact with cured adhesives containing the notified polymer, but the notified polymer will be bound within a matrix of cured solid material and is not expected to be available for further exposure.

6.2. Human Health Effects Assessment

No toxicology data were submitted for the notified polymer.

Toxicokinetics, metabolism and distribution

No toxicokinetic data were submitted. Based on the expected low water solubility (due to the predominantly hydrophobic structure) and the low molecular weight ($< 1,000$ Da) of the notified polymer, passive diffusion across the gastrointestinal (GI) tract and dermal absorption may occur. The notified polymer may also be absorbed across the respiratory tract.

The notified polymer contains functional acrylate groups. Once absorbed, acrylates are expected to be detoxified predominantly via conjugation with glutathione via the Michael addition reaction or glutathione-S-transferase. The acrylates are also likely to be hydrolysed via carboxylesterases (Patty's Toxicology, 2012).

Acute toxicity

No acute oral, dermal or inhalation toxicity studies were provided for the notified polymer. The notified polymer was estimated to be of moderate toxicity.

The acute oral toxicity of the notified polymer with shortest chain length was estimated by the notifier using the U.S. EPA TEST Software (US EPA, 2016), and the LD50 was calculated to be 1,005.76 mg/kg bw. This LD50 is considered to represent the low molecular weight species of the polymer. Therefore, the notified polymer is expected to have similar or lower acute oral toxicity.

The acute dermal toxicity of the notified polymer is not known. It is dependent on the extent of dermal absorption.

The acute inhalation toxicity of the notified polymer is also unknown; however, the notified polymer is estimated to have low vapour pressure and is not expected to form aerosols during normal use. Therefore, adverse health effects via inhalation route under normal use conditions are unlikely to occur.

Irritation and sensitisation

No data were provided for the notified polymer on eye, skin or respiratory irritation. The polymer contains methacrylate functional groups which are known to have potential to cause skin/eye irritation and skin sensitisation (US EPA, 2010). Based on the *Guide to the Classification & Labelling of UV/EB Acrylates* published by European Chemical Industry Council (Cefic, 2011), polymeric acrylates are recommended for classifications for eye and skin irritation in the absence of toxicological data.

The notified polymer contains functional acrylate groups that may have skin sensitisation potential and has > 30% species with molecular weight < 500 g/mol that may be absorbed through skin. The potential for the notified polymer to cause skin sensitisation cannot be ruled out.

The notified polymer also contains a residual monomer at > 1% concentration that is classified as Category 1 skin sensitizer under the GHS in the *Hazardous Chemical Information System (HCIS)* (Safe Work Australia, <http://hcis.safeworkaustralia.gov.au/>). The product containing the notified polymer at 45% concentration (Palatal D100 V-01) is classified as a skin sensitizer in the SDS provided.

Repeated dose toxicity

No repeat dose toxicity data were provided for the notified polymer. The potential for the notified polymer to cause adverse effects after repeated or prolonged exposure remains uncertain. However, the notified polymer is expected to undergo further polymerisation during end use, which may reduce the potential for systemic absorption after the curing process. Therefore, repeated or prolonged exposure to the notified polymer under normal use conditions is considered to be limited.

Mutagenicity/Genotoxicity

Results of a number of mutagenicity studies on acrylate and methacrylate compounds have been evaluated (Johannsen *et al.*, 2008). In general, it was found that these compounds were negative in bacterial reverse mutation assays and other *in vitro* mammalian point mutation assays. While some positive results were observed in *in vitro* mammalian clastogenicity assays, the results from *in vivo* assays were all negative. Therefore, based on the available information, the notified polymer is not likely to be genotoxic.

Carcinogenicity

The notified polymer contains several monomers that are classified as suspected carcinogens in the *Hazardous Chemical Information System (HCIS)* (Safe Work Australia, <http://hcis.safeworkaustralia.gov.au/>). However, these monomers are expected to be structurally blocked after the polymerisation and will not be available for exposure. Significant leach of the monomers due to degradation of the adhesive matrix overtime is not anticipated.

Health hazard classification

Based on the available information, the notified polymer is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

<i>Hazard classification</i>	<i>Hazard statement</i>
Acute toxicity, oral (Category 4)	H302 – Harmful if swallowed

<i>Hazard classification</i>	<i>Hazard statement</i>
Skin irritation (Category 2)	H315 – Causes skin irritation
Eye irritation (Category 2)	H319 – Causes serious eye irritation

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

The notified polymer may have potential to cause skin/eye irritation and skin sensitisation to workers. As stated by the notifier, exposure to workers is expected to be limited by the use of control measures such as mechanical closed systems and use of PPE including protective clothing, gloves and goggles.

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

The adhesive products containing the notified polymer are intended for industrial use only and will not be available to the public. Members of the public may come into contact with cured adhesive matrix containing the notified polymer. At that stage, the notified polymer is expected to be bound within the hardened matrix and will not be available for exposure.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia as component of a chemical adhesive which is used as a chemical anchoring system in the construction sector. The adhesive containing the notified polymer will not be manufactured or reformulated in Australia. Therefore, release of the notified polymer from these activities is not expected.

RELEASE OF CHEMICAL FROM USE

The finished adhesive products containing the notified polymer will be used in the construction sector for physically anchoring threaded rods, reinforcing bars or rod sleeves into concrete and masonry. The adhesive is resin mortar based and expected to be chemically stable under normal construction conditions. Application of the adhesive products containing the notified polymer will be by a hand tool, battery-operated tool or pneumatic tool with a static mixer. Once the adhesive is applied to metal articles and cured, no further potential for release or environmental exposure to the notified polymer may occur, as the notified polymer will be chemically bound within a matrix of cured solid material during the curing process.

RELEASE OF CHEMICAL FROM DISPOSAL

The adhesive is expected to be chemically stable under normal construction conditions. Once the components of the adhesive are mixed, the curing is expected to complete within several minutes to form a solidified matrix. The notified polymer in cured adhesive is expected to share the fate of the substrates to which it has been applied and is expected to be predominantly disposed of to landfill. Residues of the notified polymer in empty import containers and end-use packages, which are expected to account for 1% of the total import volume, will be disposed of to landfill along with the containers/packages.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified polymer is expected to be irreversibly cured within an inert solid matrix following its use in physical anchoring system into concrete and masonry. The majority of the notified polymer is expected to be disposed of to landfill as waste from spills, residues in empty import containers, and construction waste at the end of their useful life. The notified polymer that is disposed of to landfill is expected to remain associated with the substrate to which it has been applied and in its cured form it is not expected to be bioavailable nor biodegradable. The notified polymer in solid waste disposed of to landfill

is not likely to be mobile due to its expected limited water solubility and incorporation into an inert matrix. The notified polymer is expected to undergo slow biotic and abiotic degradation processes in landfill, to form water, and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) was not calculated as, based on its reported use pattern, significant quantities are not expected to be released to the aquatic environment.

7.2. Environmental Effects Assessment

No sufficient ecotoxicity data were provided. The acute toxicity for the notified polymer was conservatively estimated using ECOSAR based on a component monomer of the notified polymer with a user entered log K_{OW} of 5. The modelled estimates for the acute endpoints (Methacrylates SAR, ECOSAR v2.00) showed that the notified polymer is expected to be very toxic to aquatic organisms (US EPA, 2017).

7.2.1. Predicted No-Effect Concentration

A predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment

The risk quotient ($Q = PEC/PNEC$) for the notified polymer has not been calculated as release to the aquatic environment in ecotoxicologically significant quantities is not expected based on its reported use pattern. The majority of the notified polymer will eventually be disposed of to landfill following its use. In its cured state the notified polymer will be irreversibly bound into an inert matrix and is unlikely to leach or be bioavailable. On the basis of the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

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